

AMENDMENTS TO THE CLAIMS

Claim 1 (withdrawn).

- 2. (currently amended) A method for detecting malignant carcinoma, comprising:
- (a) obtaining a tissue sample from a patient;
- (b) determining the level of a p63 gene product protein in said patient sample using a p63 binding protein;
- (c) comparing the level of said p63 gene product protein in said patient sample with the level of said p63 gene product protein in a control sample of cells;

wherein a lower level of said p63 gene product protein in said patient sample as compared to the control sample is indicative of the presence of malignant carcinoma.

- β. (original) A method of claim 2, wherein said malignant carcinoma is carcinoma of the cervix, breast, salivary gland and/or prostate gland.
- 4. (previously amended) A method of claim 2, wherein said control sample is selected from the group comprising basal epithelial cells, immature squamous cells, ME 180, sub-columnar reserve cells and human foreskin keratinocytes.
- 5. (currently amended) A method of claim 2, wherein the level of said p63 gene product protein is determined by a method selected from the group comprising RT-PCR, immunoblotting, immunoprecipitation, and sandwich immunoassay.
- 6. (currently amended) A method for detecting cancer in tissues containing sub-columnar reserve cells, comprising:
 - (a) obtaining a tissue sample from a patient;
 - (b) determining the level of a p63 gene product protein in said patient sample using a p63 binding protein;
 - (c) comparing the level of said p63 gene product protein in said patient sample with the level of said p63 gene product protein in a control sample of cells;

wherein a lower level of said p63 gene product protein in said patient sample as compared to the control sample is indicative of the presence of cancer in said tissues.

7. (original) A method of claim 6, wherein said tissue containing sub-columnar reserve cells is selected from the group comprising cervical tissue, breast tissue, and/or prostate gland tissue

- 8. (original) A method of claim 6, wherein said tissue containing sub-columnar reserve cells is selected from the group comprising kidney, testis, adrenal gland, brain, spleen, and thymus.
- 9. (original) A method of claim 6, wherein said control sample is selected from the group comprising basal epithelial cells, immature squamous cells, ME 180 and human foreskin keratinocytes.
- 10. (currently amended) A method for distinguishing cervical squamous carcinoma from cervical small cell undifferentiated carcinoma, comprising:
 - (a) obtaining a cervical tissue sample from a patient;
 - (b) determining the level of a p63 gene product protein in said patient sample using a p63 binding protein;
 - (c) comparing the level of said p63 gene product protein in said patient sample with the level of said p63 gene product protein in a control sample of cervical squamous carcinoma cells;

wherein a decrease in the <u>lower</u> level of said p63 gene product <u>protein</u> in said patient sample as compared to the control sample is indicative of small cell undifferentiated carcinoma.

Claims 11 and 12 (withdrawn)

- 13. (original) A kit for diagnosing malignant carcinoma comprising a p63 specific antibody.
- 14. (original) A kit of claim 13, wherein said antibody is selected from the group comprising a TAp63-specific antibody and a Δ Np63-specific antibody.
- 15. (currently amended) The method of claim 2, wherein said p63 gene product protein is selected from the group consisting of TAp63α (SEQ ID NO: 13), TAp63β (SEQ ID NO: 14),

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TAp63 γ (SEQ ID NO: 15), ΔNp63 α (SEQ ID NO: 16), ΔNp63 β (SEQ ID NO: 17) and ΔNp63 γ (SEQ ID NO: 18).

16. (currently amended) The method of claim 10, wherein the level of said p63 gene product protein is determined by a method selected from the group comprising RT-PCR, immunoblotting, immunoprecipitation, and sandwich immunoassay.

- 17. (currently amended) The method of claim 10, wherein said p63 gene product protein is selected from the group consisting of TAp63α (SEQ ID NO: 13), TAp63β (SEQ ID NO: 14), TAp63γ (SEQ ID NO: 15), ΔNp63α (SEQ ID NO: 16), ΔNp63β (SEQ ID NO: 17) and ΔNp63γ (SEQ ID NO: 18).
- 18. (currently amended) A method for distinguishing benign prostate lesions from malignant prostate lesions, comprising:
 - (a) obtaining a prostate tissue sample from a patient;
 - (b) determining the level of a p63 gene product protein in said patient sample <u>using a p63</u> binding protein;
 - (c) comparing the level of said p63 gene product protein in said patient sample with the level of said p63 gene product protein in a control sample of basaloid prostate cells;

wherein a decrease in the <u>lower</u> level of said p63 gene product <u>protein</u> in said patient sample as compared to the control sample is indicative of small cell undifferentiated carcinoma.

- 19. (currently amended) The method of claim 18, wherein the level of said p63 gene product protein is determined by a method selected from the group comprising RT-PCR, immunoblotting, immunoprecipitation, and sandwich immunoassay.
- 20. (currently amended) The method of claim 19, wherein said p63 gene product protein is selected from the group consisting of TAp63α (SEQ ID NO: 13), TAp63β (SEQ ID NO: 14), TAp63γ (SEQ ID NO: 15), ΔNp63α (SEQ ID NO: 16), ΔNp63β (SEQ ID NO: 17) and ΔNp63γ (SEQ ID NO: 18).
- 21. (currently amended) The method of claim 19, wherein the level of said p63 gene product protein in said patient sample is at least 2000-fold lower than the level of p63 gene product protein in said control sample.

Claim 22 (withdrawn).

- 23. (new) The method of claim 2, wherein said p63 binding protein is a p63 specific antibody.
- 24. (new) The method of claim 2, wherein said p63 protein has an amino acid sequence at least 98% identical to an amino acid sequence set forth in anyone of SEQ ID NOs: 13-24.
- 25. (new) The method of claim 6, wherein said p63 binding protein is a p63 specific antibody.
- 26. (new) The method of claim 6, wherein said p63 protein has an amino acid sequence at least 98% identical to an amino acid sequence set forth in anyone of SEQ ID NOs: 13-24.
- 27. (new) The method of claim 10, wherein said p63 binding protein is a p63 specific antibody.
- 28. (new) The method of claim 10, wherein said p63 protein has an amino acid sequence at least 98% identical to an amino acid sequence set forth in anyone of SEQ ID NOs: 13-24.
- 29. (new) The method of claim 18, wherein said p63 binding protein is a p63 specific antibody.
- 30. (new) The method of claim 18, wherein said p63 protein has an amino acid sequence at least 98% identical to an amino acid sequence set forth in anyone of SEQ ID NOs: 13-24.